



NDA 206321/S-009

SUPPLEMENT APPROVAL

Novo Nordisk, Inc.
Attention: Patricia Robson
Senior Manager, Regulatory Affairs
P.O. Box 846
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Ms. Robson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 30, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Saxenda (liraglutide) injection, 3 mg.

This sNDA provides for proposed modifications to the approved Saxenda risk evaluation and mitigation strategy (REMS). This supplement is in response to our November 26, 2018, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Saxenda was originally approved on December 23, 2014, and the most recent modification was approved on May 22, 2017. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated November 26, 2018.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Saxenda outweigh its risks because the communication plan has been completed and because the most recent assessment demonstrates that the communication plan has met its goals. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Saxenda.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Martin White, M.S., Regulatory Project Manager, at (240) 402-6018.

Sincerely,

{See appended electronic signature page}

William Chong, M.D.
Deputy Director (Acting)
Division of Metabolism and Endocrinology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

WILLIAM H CHONG
12/04/2018